K092623

OCT 30 2009

510(k) Summary for the F.A.S.T.™ SED and CXD System

I. General Information

Submitter:	Genesis Medical Interventional, Inc. 2801 Bering Drive Suite X San Jose, CA 95131
Contact Person:	Anne C. Worden VP, Regulatory & Quality Assurance
Summary Preparation Date:	August 23, 2009

II. Names

Device Names:	F.A.S.T.™ SED and CXD System
Primary Classification Name:	Embolectomy Catheter

III. Predicate Device

- Genesis Medical Interventional™ F.A.S.T.™ (Facilitated Aspiration/Suction Thrombectomy) System (K040010)

IV. Product Description

The F.A.S.T.™ System – SED (Self-Expanding Device) and F.A.S.T.™ System – CXD (Controlled Expansion Device) are sterile, disposable, thrombectomy systems for the non-surgical removal of emboli and thrombi from blood vessels or grafts.

The F.A.S.T.™ System – SED consists of a self-expanding nitinol basket mounted on a core wire. The device is compressed and sheathed in an introducer designed to facilitate loading and advancement of the device into the proximal hub of an 0.021-in (0.533-mm) microcatheter. When advanced to the distal end of a microcatheter, the compressed basket is deployed by withdrawing the microcatheter over the basket. The basket may be reconstrained back into the microcatheter.

The F.A.S.T.™ System – CXD Device consists of an expandable nitinol basket mounted on a hollow tube and core wire. Basket expansion and contraction to the desired diameter is controlled by the operator at the proximal end of the device. Using the handle control, the basket is contracted prior to withdrawing the device back into the microcatheter.

Both the F.A.S.T.™ System – SED and the F.A.S.T.™ System - CXD have markers at the proximal and distal ends of the basket to facilitate visualization under fluoroscopy and are compatible with 0.021 inch (0.533-mm) inner diameter (ID) microcatheters.

V. Indications for Use

The F.A.S.T.™ System SED and CXD are indicated for:

- The non-surgical removal of emboli and thrombi from blood vessels.
- The non-surgical removal of thrombi from synthetic grafts.
- Temporary use in vessel/graft occlusions.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a vessel/graft.
- Catheter placement over a guidewire.

VI. Rationale for Substantial Equivalence

The F.A.S.T.™ System SED and CXD share the same or similar: indications for use, fundamental scientific technology, general device operation, materials, sterilization process, and packaging requirements, and, therefore, are substantially equivalent for use in minimally invasive vascular applications to the Genesis Medical Interventional™ F.A.S.T.™ (Facilitated Aspiration/Suction Thrombectomy) System (K040010). In addition, verification activities demonstrated adequate device performance.

VII. Safety and Effectiveness Information

Verification testing conducted on the F.A.S.T.™ System SED and CXD demonstrates the devices are substantially equivalent to the predicate device and do not raise new questions regarding safety and effectiveness with respect to embolectomy catheters when used in accordance with the Instructions for Use.

VIII. Conclusion

As described in this 510(k) Summary, the F.A.S.T.™ System SED and CXD are substantially equivalent to the to the Genesis Medical Interventional™ F.A.S.T.™ (Facilitated Aspiration/Suction Thrombectomy) System based on a comparison of intended uses and the results of *in-vitro* and *in-vivo* testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OCT 30 2009

Genesis Medical Interventional, Inc.
c/o Ms. Anne Worden
Vice President of Regulatory & Quality Assurance
2081 Bering Drive
San Jose, CA 95131

Re: K092623
Trade/Device Name: F.A.S.T.™ System SED and CXD
Common Name: Catheter, Thrombectomy
Regulation Number: 21 CFR 870.5150
Regulatory Class: II
Product Code: DXE
Dated: September 29, 2009
Received: September 30, 2009

Dear Ms. Worden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. S. Kellermann

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K092623

Device Name: F.A.S.T.™ System SED and CXD

Indications for Use: The F.A.S.T.™ System SED and CXD are indicated for:

- The non-surgical removal of emboli and thrombi from blood vessels.
- The non-surgical removal of thrombi from synthetic grafts.
- Temporary use in vessel/graft occlusions.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a vessel/graft.
- Catheter placement over a guidewire.

Prescription Use___X____ AND/OR Over-the-Counter Use_____
(Per 21 C.F.R. 801 Subpart D) (21 C.F.R. 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hollebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

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